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ABSTRACT:

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(54) IMPROVEMENTS IN AND RELATING TO INFUSION CANNULA APPARATUS

(71) We, DAMECO MEDICAL PRODUCTS AKTIEBOLAG, a Swedish Company, of Storgatan 37, 152 00 Strangnas, Sweden, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to infusion cannula apparatus.

The invention consists in a valve (1) for use in infusion cannula apparatus including a casing (3) and a valve body (4) which fits into, and is retained rotatably in, the casing (3) by means of an annular seal, which seal includes a slot (13) in one of the casing (3) and body (4) and a bulge (18) on the other for fitting in the slot (13), each of the valve body (4) and the casing (3) having an axially facing opening and wall portions (part 5 in respect of the casing) around and axially opposite the opening to define an internal space (16 in respect of the valve body), said opening of the valve body (4) facing into the said internal space (of part 5) of the casing (3), there being in the valve (1) at least two inlets (6, 7) to which connection means (31) for connecting a supply of infusion fluids can be sealingly connected and an outlet (8) connectable by the valve body (4) to either of the inlets (6, 7), to which outlet (8) there can be sealingly connected catheter means (2), the valve body (4) and the casing (3) being so shaped as to permit a cannula (20) to be introduced through one of the inlets (6) and the outlet (8) into the catheter means (2).

Preferably, said internal space of the valve body forms a common chamber (16) for connection to the inlets (6, 7) and outlet (8) by way of gate slots (17) open at said opening of the valve body and extending through said of said wall portions of the valve body (4).

Preferably, the casing (3) has an annular groove (defined around boss 12) inside its said wall portion opposite its said opening in which groove the said wall portions around the said opening of the valve body is guided.

Preferably, the valve is a three-way valve with each of the inlets (6, 7) and outlet (8) arranged perpendicular to another thereof and passageways (17) in the valve body (4) for leading thereto arranged likewise.

Preferably, the valve has on the valve body (4) at least three handle pins (15) whose directions correspond to the locations of passageways (17) in the valve body (4) for leading to the inlets (6, 7) and outlet (8), thereby forming an indicator for flow pattern through the valve (1).

Preferably, the valve body (4) includes a member having an axial bore (16^1) that is open at one end to the outside of the valve (1) and that includes the said internal space of the valve body of which said wall portion opposite its said opening is formed by a diaphragm formed by a member (32) which is hollow so as to define a space open to the outside of the valve.

Preferably, the diaphragm is made of resilient material and in the part thereof furthest from its said opening is formed with a short and narrow slit (34) which will open at pressure from the outside of the valve (1) and which will close when the pressure within the valve (1) is the same as or exceeds the pressure at the outside of the valve (1).

Infusion cannula apparatus embodying the invention may include any such valve (1) and the catheter means (2) mentioned above.

Preferably, the catheter means (2) locks to the said outlet (8) by virtue of an annular seal that includes a slot (27) in one of the catheter means (2) and valve (1), and a bulge (11) on the other for fitting in this slot (27).

Preferably, the catheter means (2) includes a connection member (23) suitable for being engaged with the said outlet (8) and a catheter (22) sealingly fixed to the connection member (23).

[*Price 25p*]

The apparatus may include the cannula (20) mentioned above.

The apparatus mentioned above may be in the form of a kit of parts or in the form of an assembly.

The references in brackets identify examples of the respective elements to be seen in the accompanying drawings.

The term "cup shape" used herein of a member implies that the member has an internal space defined by wall portions of the member around and opposite an opening thereof, and applies for example to the part of body 4 surrounding its lower cavity as seen in Figure 4. The open end of each cup shape is herein called its mouth and the other end its base.

When the apparatus is assembled it serves for the introduction of an infusion fluid through the catheter means from either of the inlets of the valve.

Within the medical field treatments are being used to an ever increasing extent in which medical compounds are introduced into a patient intraveneously or in which samples of blood are taken at short intervals. Consequently the patient is often supplied with blood or other infusion fluids, or has to supply blood, on several occasions within a fairly short period of one or two days or even a period of up to several weeks. In order to avoid too many punctures of the vein of the patient with all the problems and disadvantages involved therein it has been common after an intravenous infusion of some fluid into the patient to leave the infusion cannula within the patient in order that this might be utilized at subsequent infusions of the same or another fluid.

The infusion cannula is usually made of steel or any other stiff material and it is therefore of the greatest importance that the part of the body into which the cannula has been introduced and left is not bent since in that case pain and injuries may arise in the patient. In order to prevent such bending of said part of the body, usually the arm, this is often strapped to a sheet of wood or any other non-bendable material. This is irritating and sometimes painful to the patient and there has therefore been a need for a cannula assembly for infusion purposes where the cannula may be left within the patient for long periods without causing the patient essential discomfort or pain. There has also been a need for the cannula assembly to be so formed that one and the same cannula might be used for infusing various fluids alternatively or at the same time.

The embodiments described below are useful in helping to overcome these difficulties. The bulge 18 and slot 13 form a labyrinthine seal that helps to avoid risk of air being forced into the valve and led into the vein of the patient whereby risk arises of air embolism or other complications.

In these embodiments the infusion cannula assembly is formed with a tap valve to which a catheter of a bendable material is attached and in which a cannula of steel or any other suitable material may be inserted through the valve and so far through the catheter that the point of the cannula projects somewhat outside the mouth of the catheter. At the introduction of said infusion arrangement into the vein of the patient the cannula will puncture the vein whereupon the catheter which closely surrounds the cannula may be introduced into the vein. When the catheter is thus positioned in the vein the cannula is retracted and the valve is thus connected to the blood system of the patient through the bendable catheter. The bendable catheter causes the patient very little discomfort and blood or alimentation fluid may easily be supplied to the patient alternatively or at the same time by means of the three-way-valve.

Further, there is often a need to supply some further fluid to the patient, for instance some injection fluid intravenously, preferably in a strictly predetermined amount, by means of the infusion assembly. In one of the embodiments the valve is therefore provided with an axial bore leading to the catheter and sealingly closed by means of a rubber or like diaphragm. Previously, diaphragms have been known that are designed to be punctured by the point of an injection syringe by force before the fluid can be injected into the patient. At the introduction of the syringe point it may however happen that particles of the rubber or other diaphragm material may be torn away from the diaphragm and thereby the risk arises that such particles torn away may be led into the blood system of the patient. On the contrary, the diaphragm shown in Figs. 4 and 5 is designed not to be puncturable, but instead to include a slit 34 of the kind mentioned above for introducing the injection fluid.

Reference will now be made by way of example to the accompanying drawings, in which:—

Figure 1 is an exploded perspective view of infusion cannula apparatus embodying the invention;

Figure 2 is a vertical cross-section through the assembled apparatus according to Figure 1 seen along the line II—II of Figure 1;

Figure 3 is an underneath plan of the valve body 4 of Figures 1 and 2;

Figure 4 is a cross-section similar to that of Figure 2, but of a second embodiment of the invention;

Figure 5 is a detail of Figure 4, seen under two different conditions; and

Figure 6 is a schematic diagram showing

the function of the assembly at various positions of the valve.

Referring to the drawings, the infusion cannula assembly comprises a tap valve 1 having a catheter means 2 detachably connected thereto. The terms "top", "bottom" and the like used herein refer to the orientation seen in the drawings.

The tap valve comprises a valve casing 3 having a valve tap fit thereinto. The valve casing 3 is composed of a cup-shaped part 5 open at the top and having two inlets 6 and 7 for infusion fluids and an outlet 8 for the connection of the catheter means 2, all having the form of nozzles. The part 5 of the valve casing is closed at its bottom and the three connection nozzles 6, 7 and 8 extend radially out from the part 5 adjacent to the bottom thereof and they are spaced 90° with respect to each other with the inlet nozzle 6 and the outlet nozzle 8 located diametrically opposite to each other The inlet nozzles 6 and 7 are substantially cylindrical and are formed with an inner bore 9 which contracts conically at the inner part thereof and which opens to the inner and lowermost part of the part 5. The inlet nozzles are further formed with a flange 10 at the outer ends thereof which is square, in the manner shown in Fig. 1, and the edges of which are slightly longer than the outer diameter of the cylindrical part of the nozzle. The purpose of the flange 10 is to serve as a holder for a protection cup for each of the inlet nozzles as will be further explained below.

The outlet nozzle 8 tapers outside to provide a conical clamping seat for the catheter means 2 and hence a good seal. Both for preventing undue movement apart of the catheter means 2 and the valve 1 and for establishing a labyrinthine seal, the outlet nozzle 8 is formed with an annular bulge 11 adapted to be sealingly engaged with a corresponding annular slot 27 of the catheter means 2. Also, the outlet nozzle 8 is formed with a bore, opening into the inner and lowermost part of the part 5. It is important that the bores of the inlet nozzle 6 and the outlet nozzle 8 extend in alignment with each other for enabling thereby the introduction of a cannula 20 straight through the whole of the valve body 4 and the two nozzles 6 and 8 as will be further explained below. At its bottom the valve casing 3 is formed inside with a frusto-conical boss 12, the purpose of which is to define a groove to stabilize and centre the lower part of the valve body 4 and to enable a sealing clamping of the walls thereof against the inner walls of the valve casing 3. At a point somewhat above the bores 9 of the connection nozzles the valve casing 3 is formed with an annular slot 13, the purpose of which is both to prevent undue movement apart of the valve body 4 and the valve casing 3, and to establish a labyrinthine seal in order to reduce the risk of leakage. In order to further increase the sealing between the valve body 4 and the valve casing 3 the valve casing is, at its uppermost part, formed with a bevel 14 diverging upwardly and the valve body 4 is formed with a corresponding bevel.

The valve body 4 is substantially cylindrical and a lower part thereof forms the part giving the valve action while the upper part thereof is formed as a handle having three handle pins 15. The handle pins are provided radially and perpendicular to each other and the purpose thereof is that the handle pins shall also serve as an indicator of the fluid direction through the valve. The positions of the handle pins consequently correspond to the location of passages 17 and, in one orientation of valve body 4, of the inlet nozzles 6 and 7 and the outlet nozzle 8. In the lower part thereof the valve body 4 is formed with an axial bore 16 extending somewhat upwards and the valve wall is intersected by three radial gate slots 17 forming the aforesaid passages and extending from the bottom of the valve body 4 to a point level with or slightly above the upper edge of the inlet passages formed by the bores of the connection nozzles 6, 7 and 8. The slots 17 are provided perpendicularly to each other and in axial alignment with the handle pins of the handle 15. Level with the annular slot 13 of the valve casing 3 the valve body 4 is formed with a corresponding annular bulge 18 and level with the bevel 14 of the valve casing 3 the valve body 4 is as stated above formed with a correspondingly bevelled part 19.

Both the valve casing 3 and the valve body 4 are preferably made of some resilient material and a suitable material for this purpose has been found to be thermoplastics resin, for instance resin of the group of resins called polyamide plastics, ethene plastics, tetrafluoroethane plastics or the like. Such synthetic resins possess the advantage of both being somewhat resilient and having self-lubricating properties and hence there is no risk that the valve tap will get stuck in the valve housing even if it is clamped fairly hard therein.

The mounting of the valve body 4 in the valve casing 3 is effected simply by forcing the valve body 4 with a suitable pressure axially into the valve casing 3 until the annular bulge 18 has come into position in the corresponding annular slot 13 of the valve casing 3.

In a preferred embodiment of the invention the bores 9 of the inlet nozzles 6 and 7 are formed with a size and draught corresponding to a general standard and they are suitably formed according to the "LUER-

standard", whereby ordinary needles, syringes and the similar may be used in connection with the cannula assembly.

The catheter means 2 includes a catheter 22 and a connection member 23, into which catheter a pointed cannula 20 of known kind, of steel or a similar material, provided with a connection tube 21 may be introduced.

As stated above the cannula 20 is of known kind and may have any suitable size. The cannula 20 is cast into or glued to the connection tube 21, and the fluid passageway of the cannula opens into a corresponding bore 24 of the tube 21. In order to establish a good seal between the cannula and the valve casing 3 the cannula connection tube 21 is formed with a tapered part 25 adapted to the corresponding tapered part of the inlet nozzle 6. A snap locking means such as the annular seal in the outlet nozzle 8 should not be present at the inlet nozzle 6, since this would obstruct the pulling out of the cannula 20 after the insertion of the catheter 22 into a vein of the patient.

The catheter 22 which is made as a thin wall tube of a flexible material, preferably polytetrafluoroethylene (e.g. as sold under the Trade Mark TEFLON) or polyethylene is sealingly attached to the connection member 23. The size of the catheter should be adapted to the size of the cannula 20, so that said cannula 20 may be introduced through the catheter 22 with a good seal, but without difficulty. The catheter passage-way opens into a passage-way 26 of the connection member 23 and this latter passage-way widens towards the valve to form a tapered passage-wty adapted to the outlet nozzle 8 and formed with an annular slot 27 corresponding to the bulge 11 of the outlet nozzle 8. The connection member 23 is further formed with a pair of curved wings 28 by means of which the cannula assembly may be attached for instance to the arm of a patient by means of plaster or the like.

The catheter means 2 may be connected to the valve 1 by forcing the connection member 23 axially against the outlet nozzle 8 of the valve until the bulge 11 engages the slot 27. The valve body 4 is adjusted for straight line flow through the valve, i.e. as indicated in Figure 6*d* and the cannula 20 is introduced through the inlet nozzle 6, the valve part 5, the outlet nozzle 8, the connection member 23 and the catheter 22. In its fully inserted position the cannula should project a little distance out of the catheter 22. For facilitating the insertion of the catheter into a vein which has been pierced by the cannula the outer end of the catheter is bevelled to merge smoothly with the outer surface of the cannula. Preferably said bevelled outer end of the catheter 22 is somewhat shrunk to assure a good seal between this part of the catheter and the cannula.

On the insertion of the above described infusion cannula into a vein of the patient the part of the cannula 20 projecting outside the catheter 22 will pierce the vein, and on the further insertion of the cannula the catheter 22 will be forced into the vein. In order to avoid waste of blood or the like the connection tube 21 of the cannula is preferably formed with a receptacle for blood (not indicated in the drawings). Such a receptacle may for instance be a plastics bag or the like which has been tied around the connection tube. As soon as the catheter is in its proper position in the vein the cannula may be retracted and the valve is closed, i.e. the valve tap is turned one eighth of a full turn in the clockwise direction so as to take the position indicated in Figure 6*e*. Thereafter connection means for blood may be connected for instance to the inlet nozzle 6 and connection means for infusion fluid or the like to the inlet nozzle 7. When the patient is then to be supplied with blood the valve tap is turned to the position indicated in Figure 6*d*, and when the patient is to be supplied with infusion fluid the valve tap is turned to the position indicated in Figure 6*a*. The valve assembly also offers the possibility of introducing blood and infusion fluid at the same time into the patient and in such case the valve tap is turned into the position indicated in Figure 6*b*. Thereby blood and alimentation fluid will be supplied at the same time through the catheter 22 after having been mixed in the valve part 5. The position indicated in Figure 6*c* is used mainly for washing or cleaning of the valve, particularly the inlet nozzles 6 and 7. Of course, blood or alimentation fluid may be supplied through either of the inlet nozzles 6 and 7.

It is to be noted that the cannula assembly causes the patient very little discomfort since the catheter 22 is made of a flexible material. Even if the cannula assembly is left attached to the arm or other part of the patient it does not to any great extent impede the movements of the patient and therefore the cannnula assembly may without any great disadvantage be left attached to the patient for a period of several weeks.

When the supply of blood and/or alimentation fluid is to cease the valve tap is turned as indicated in Figure 6*e*, so that the various flows through the valve cease. In certain cases it may at this stage be suitable to wash the valve clean which is possible by adjusting the valve tap as indicated in Figure 6*c* as mentioned above. For protecting the inlet nozzles 6 and 7 against impurities when blood or alimentation fluid is not supplied the inlet nozzles are provided with protection caps 29, one of which is best shown in

Figure 4. The protection cap 29 is formed with an inner cap 30, which is slightly tapered like the bore 9 of the inlet nozzle 7. When the cap 29 is mounted on the inlet nozzle this is sealed very effectively at the same time as the outer surfaces thereof are protected by the jacket of the cap.

Often it may be wished to supply some further form of infusion fluid to the patient by the cannula assembly, and this may easily be done by means of a syringe, for instance the syringe 31 indicated with dotted lines in Figure 2 which may, without a needle, be connected directly to either of the two inlet nozzles.

Sometimes it may, however, be wished to give the patient blood as well as alimentation fluid and a third infusion fluid at the same time. For this purpose the embodiment of the invention shown in Figures 4 and 5 is well suited. From Figure 4 it is evident that the valve body 4 is formed with an axial bore 16^1 and in the upper part of said bore a diaphragm formed by a diaphragm member 32 of rubber or a similar material is mounted. The diaphragm member 32 is sealingly engaged with the bore 16^1 of the valve body 4 and it is formed with a radially projecting flange 33 adapted to engage the upper edge of the valve body 4. The diaphragm member is designed not to be puncturable. On the contrary, in the lowermost part of the diaphragm a thin and narrow slit 34 has been preformed. The slit 34 is as narrow and thin as required to completely seal against penetration of air, fluid or particles into the inner part of the valve at normal pressure from the outside. The upper part of the bore 16^1 may, like the diaphragm member 32, be made according to the above mentioned "LUER-taper standard" or any other suitable standard in order that a syringe without a needle may be connected with a good seal to the top of the diaphragm 32. The valve diaphragm will thereby form an injection valve. Figure *5a* shows the action upon injection through the diaphragm and Figure *5b* shows the function upon infusion through the inlet nozzles 6 and 7. Thus, when the syringe has been connected to the diaphragm member 32 and the injection fluid is forced towards the top of the diaphragm member the lower cup-shaped part, i.e. the diaphragm proper, thereof is forced to widen somewhat, whereby the slit 34 opens and lets the injection fluid into the inside of the valve. As soon as the pressure from the syringe ceases the slit 34 recloses and prevents further injection fluid from penetrating into the valve and blood and infusion fluid from escaping from the valve to the top of the diaphragm member 32.

If only the inlet nozzles 6 and 7 are used (i.e. infusion alone) the case indicated in Figure *5b* occurs, whereby the fluid under pressure existing within the valve will cause a pressure upwards in the direction of the arrow against the cup-shaped part of the diaphragm member. This part will thereby become somewhat compressed by a pressure which will increase with the rise in pressure of the fluid within the valve. This will give high safety against leakage even at fairly high pressures within the valve. In Figure *5b* the normal position of the valve diaphragm has been indicated by dotted lines while its pressure actuated position has been indicated by continuous lines. Preferably, the valve diaphragm member 32 is also provided with some suitable form of protection means for preventing defiling of the top of the diaphragm member when no injection takes place.

WHAT WE CLAIM IS:—

1. A valve for use in infusion cannula apparatus including a casing and a valve body which fits into, and is retained rotatably in, the casing by means of an annular seal, which seal includes a slot in one of the casing and body and a bulge on the other for fitting in the slot, each of the valve body and the casing having an axially facing opening and wall portions around and axially opposite the opening to define an internal space, said opening of the valve body facing into the said internal space of the casing, there being in the valve at least two inlets to which connection means for connecting a supply of infusion fluids can be sealingly connected and an outlet connectable by the valve body to either of the inlets, to which outlet there can be sealingly connected catheter means, the valve body and the casing being so shaped as to permit a cannula to be introduced through one of the inlets and the outlet into the catheter means.

2. A valve as claimed in Claim 1, in which said internal space of the valve body forms a common chamber for connection to the inlets and outlet by way of gate slots open at said opening of the valve body and extending through some of said wall portions of the valve body.

3. A valve as claimed in Claim 1 or 2, in which the casing has an annular groove inside its said wall portion opposite its said opening in which groove the said wall portions around the said opening of the valve body is guided.

4. A valve as claimed in Claim 1, 2 or 3, that is a three-way valve with each of the inlets and outlet arranged perpendicular to another thereof and passageways in the valve body for leading thereto arranged likewise.

5. A valve as claimed in any preceding Claim, having on the valve body at least three handle pins whose directions correspond to the locations of passageways in the valve body for leading to the inlets and

outlet, thereby forming an indicator for flow pattern through the valve.

6. A valve as claimed in any preceding Claim, in which the valve body includes a member having an axial bore that is open at one end to the outside of the valve and that includes the said internal space of the valve body of which said wall portion opposite its said opening is formed by a diaphragm formed by a member which is hollow so as to define a space open to the outside of the valve.

7. A valve as claimed in Claim 6, in which the diaphragm is made of resilient material and in the part thereof furthest from its said opening is formed with a short and narrow slit which will open at pressure from the outside of the valve and which will close when the pressure within the valve is the same as or exceeds the pressure at the outside of the valve.

8. A valve substantially according to any embodiment hereinbefore described with reference to the accompanying drawings.

9. Infusion cannula apparatus including a valve as claimed in any one of Claims 1 to 7, and the catheter means mentioned in Claim 1.

10. Apparatus as claimed in Claim 9, in which the catheter means locks to the said outlet by virtue of an annular seal that includes a slot in one of the catheter means and valve, and a bulge on the other for fitting in this slot.

11. Apparatus as claimed in Claim 9 or 10, in which the catheter means includes a or 11, including the cannula mentioned in connection member suitable for being engaged with the said outlet and a catheter sealingly fixed to the connection member.

12. Apparatus as claimed in Claim 9, 10 Claim 1.

13. Infusion cannula apparatus including a valve as claimed in any one of Claims 1 to 7 and the cannula mentioned in Claim 1.

14. Infusion cannula apparatus including a valve, and including catheter means and/or a cannula, the apparatus being substantially according to any embodiment hereinbefore described with reference to the accompanying drawings.

15. Apparatus as claimed in any one of Claims 9 to 14, in the form of a kit of parts.

16. Apparatus as claimed in any one of Claims 9 to 14, in the form of an assembly.

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1344166 COMPLETE SPECIFICATION
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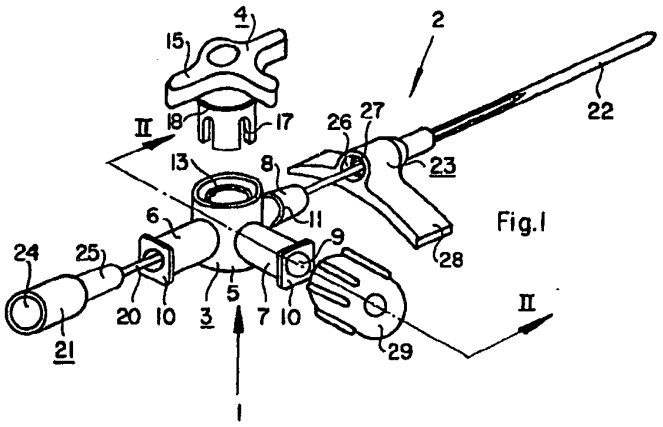

Fig.1

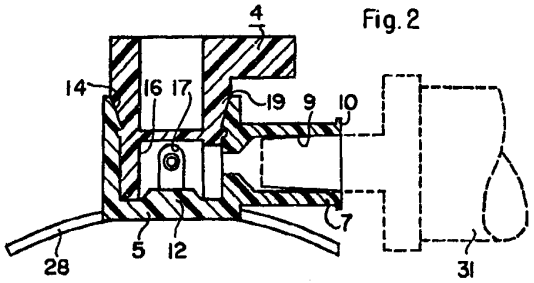

Fig. 2

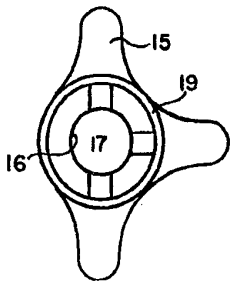

Fig. 3

1344166 COMPLETE SPECIFICATION
2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 2

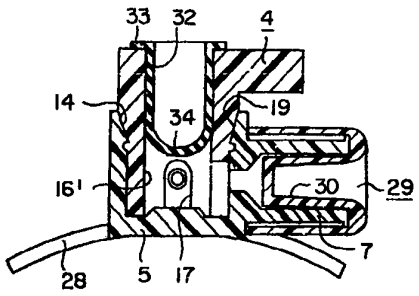

Fig. 4

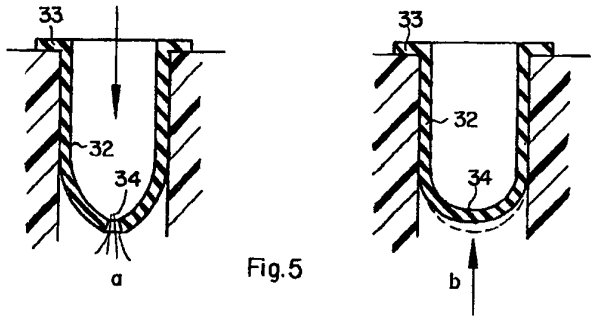

Fig. 5

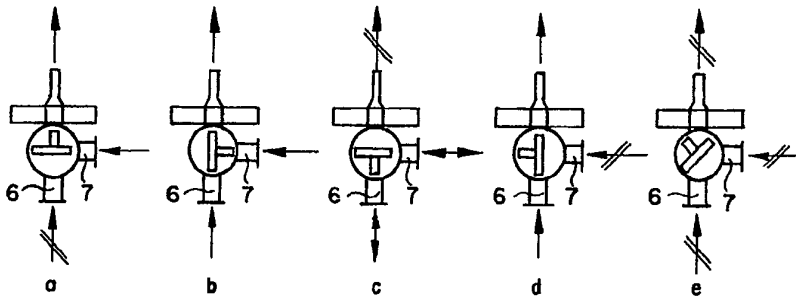

Fig. 6